

|  |   |                                     |   |
|--|---|-------------------------------------|---|
| <b>FORM PTO-1449 (Modified)</b><br><br><b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT</b><br><br>(Use several sheets if necessary) | <b>ATTY. DOCKET NO.</b><br><br>14918-707 CPA4 | <b>SERIAL NO.</b><br><br>08/846,933 | RECEIVED<br>ECH CENTER 1500/2000<br>99 AUG - 6 AM 10:30 |
|  | <b>APPLICANT</b><br>Cleland et al.            |                                     |   |
|  | <b>FILING DATE</b><br>April 30, 1997          | <b>GROUP ART UNIT</b><br>1641       |   |

**REFERENCE DESIGNATION**
**U.S. PATENT DOCUMENTS**

| EXAM'R INITIAL |     | DOCUMENT NUMBER | DATE     | NAME              | CLASS | Subclass | Filing Date If Appropriate |
|----------------|-----|-----------------|----------|-------------------|-------|----------|----------------------------|
| VR             | 1   | 3,565,559       | 02.23.71 | Sato et al.       | 424   | 37       |                            |
| VR             | 2   | 3,737,337       | 06.05.73 | Schnoring et al.  | 117   | 100      |                            |
| VR             | *3  | 4,293,539       | 10.06.91 | Ludwig et al.     | 424   | 19       |                            |
| VR             | 4   | 4,389,330       | 06.21.83 | Tice et al.       | 427   | 213.36   |                            |
| VR             | *5  | 4,524,067       | 06.18.85 | Archi et al.      | 514   | 33       |                            |
| VR             | 6   | 4,568,559       | 02.04.86 | Nuwayser et al.   | 427   | 3        |                            |
| VR             | 7   | 4,637,905       | 01.20.87 | Gardner           | 264   | 4.3      |                            |
| VR             | *8  | 4,652,441       | 03.24.87 | Okada et al.      | 424   | 19       |                            |
| VR             | 9   | 4,675,189       | 06.23.87 | Kent et al.       | 424   | 490      |                            |
| VR             | *10 | 4,719,246       | 01.12.88 | Murdoch et al.    | 521   | 134      |                            |
| VR             | *11 | 4,728,721       | 03.01.88 | Yamamoto et al.   | 528   | 361      |                            |
| VR             | *12 | 4,767,628       | 08.30.88 | Hutchinson et al. | 424   | 426      |                            |
| VR             | *13 | 4,849,228       | 07.18.89 | Yamamoto et al.   | 424   | 457      |                            |
| VR             | *14 | 4,897,268       | 01.30.90 | Tice et al.       | 424   | 422      |                            |
| VR             | *15 | 4,902,515       | 02.20.90 | Loomis et al.     | 424   | 486      |                            |
| VR             | *16 | 4,917,893       | 04.17.90 | Okada et al.      | 424   | 423      |                            |
| VR             | 17  | 4,919,929       | 04.24.90 | Beck et al.       | 424   | 88       |                            |
| VR             | *18 | 4,954,298       | 09.04.90 | Yamamoto et al.   | 264   | 4.6      |                            |
| VR             | *19 | 4,962,091       | 10.09.90 | Eppstein et al.   | 514   | 2        |                            |
| VR             | *20 | 4,990,336       | 02.05.91 | Silvestri et al.  | 424   | 426      |                            |
| VR             | *21 | 5,008,116       | 04.16.91 | Cahn              | 424   | 491      |                            |
| VR             | 22  | 5,015,476       | 05.14.91 | Cochrum et al.    | 424   | 423      |                            |
| VR             | *23 | 5,057,540       | 10.15.91 | Kensil et al.     | 514   | 25       |                            |
| VR             | 24  | 5,068,112       | 11.26.91 | Samejima, et al.  | 424   | 495      |                            |
| VR             | *25 | 5,075,109       | 12.24.91 | Tice et al.       | 424   | 88       |                            |
| VR             | 26  | 5,100,669       | 03.31.92 | Hyon et al.       | 424   | 426      |                            |
| VR             | 27  | 5,126,147       | 06.30.92 | Silvestri et al.  | 424   | 497      |                            |

|  |                              |
|--|------------------------------|
| EXAMINER <i>V.R.</i>   | DATE CONSIDERED <i>10/99</i> |
| <b>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s).</b> |                              |

|  |                                      |                               |
|--|--------------------------------------|-------------------------------|
|  | <b>ATTY. DOCKET NO.</b>              | <b>SERIAL NO.</b>             |
|  | 14918-707 CPA4                       | 08/846,933                    |
|  | <b>APPLICANT</b><br>Cleland et al.   |                               |
|  | <b>FILING DATE</b><br>April 30, 1997 | <b>GROUP ART UNIT</b><br>1641 |

RECEIVED  
 TECH CENTER 1500  
 99 APR - 5 AM 10:36

|    |     |           |          |                 |     |      |  |
|----|-----|-----------|----------|-----------------|-----|------|--|
| VR | *28 | 5,198,533 | 03.30.93 | Schally et al.  | 530 | 313  |  |
| VR | 29  | 5,242,686 | 09.07.93 | Chu et al.      | 424 | 92   |  |
| VR | 30  | 5,348,867 | 09.20.94 | Georgiou et al. | 435 | 69.7 |  |
| VR | 31  | 5,624,612 | 04.29.97 | Sewall et al.   | 264 | 4.1  |  |
| VR | 32  | 5,643,605 | 07/01/97 | Cleland et al.  | 424 | 489  |  |
| VR | 33  | 5,667,808 | 09/16/97 | Johnson et al.  | 424 | 501  |  |

#### FOREIGN PATENT DOCUMENTS

| EXAM'R<br>INITIAL |     | DOCUMENT NUMBER      | DATE                | COUNTRY                       | CLASS | Subclass | TRANSLATN |    |
|-------------------|-----|----------------------|---------------------|-------------------------------|-------|----------|-----------|----|
|                   |     |                      |                     |                               |       |          | yes       | no |
| Not Available     | *34 | <del>7,992,987</del> | <del>04.01.88</del> | <del>AU (abstract only)</del> |       |          |           |    |
| VR                | 35  | 266,119 A2           | 05.04.88            | EPO                           |       |          |           |    |
| VR                | *36 | 279,688 A2           | 08.24.88            | EPO                           |       |          |           |    |
| VR                | *37 | 333,523 A2           | 09.20.89            | EPO                           |       |          |           |    |
| VR                | 38  | 399,843 A2           | 11.28.90            | EPO                           |       |          |           |    |
| VR                | *39 | 442,671 A2           | 08.21.91            | EPO                           |       |          |           |    |
| VR                | *40 | WO 90/03984          | 04.19.90            | PCT                           |       |          |           |    |
| VR                | 41  | WO 90/09166          | 08.23.90            | PCT                           |       |          |           |    |
| VR                | 42  | WO 91/12882          | 09.05.91            | PCT                           |       |          |           |    |
| VR                | *43 | WO 91/15238          | 10.17.91            | PCT                           |       |          |           |    |
| VR                | 44  | WO 93/07861          | 04.29.93            | PCT                           |       |          |           |    |
| Not Available     | 45  | <del>8,803,621</del> | <del>04.13.90</del> | <del>SE</del>                 |       |          |           |    |

#### OTHER ART (Include Author, Title, Date, Pertinent Pages, etc.)

|    |     |   |
|----|-----|---|
| VR | *46 | Arthur et al., "Challenge of chimpanzees (Pan troglodytes) immunized with human immunodeficiency virus envelope glycoprotein gp120" <u>Journal of Virology</u> 63 (12) : 5046-5053 (1989)             |
| VR | *47 | Berman et al., "Human Immunodeficiency virus type 1 challenge of chimpanzees immunized with recombinant envelope glycoprotein gp120" <u>Proc. Natl. Acad. Sci. USA</u> 85(14) : 5200-5204 (July 1988) |
| VR | *48 | Chang et al., "Biodegradable Semipermeable Microcapsules Containing Enzymes, Hormone, Vaccines, and Other Biologicals" <u>J. Bioengineering</u> 1:25-32 (1976)  |

|   |                              |
|---|------------------------------|
| EXAMINER <u>V. R.</u>   | DATE CONSIDERED <u>10/99</u> |
| <b>EXAMINER:</b> Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance <i>and</i> not considered. Include copy of this form with next communication to Applicant(s). |                              |

|  |   |                                     |
|--|---|-------------------------------------|
| <b>FORM PTO-1449 (Modified)</b><br><br><b>LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT(S)' INFORMATION DISCLOSURE STATEMENT</b><br><br>(Use several sheets if necessary) | <b>ATTY. DOCKET NO.</b><br><br>14918-707 CPA4 | <b>SERIAL NO.</b><br><br>08/846,933 |
|  | <b>APPLICANT</b><br>Cleland et al.            |                                     |
|  | <b>FILING DATE</b><br>April 30, 1997          | <b>GROUP ART UNIT</b><br>1641       |

RECEIVED  
 TECH CENTER 1600/1900  
 99 AUG - 6 AM 11:37

|               |     |   |
|---------------|-----|---|
|               | *49 | Chen Science 262:980-981 (1993)   |
| VR            | 50  | Cohen, J., "Jitters Jeopardize AIDS Vaccine Trials" Science 262:980-981 (1993)  |
| VR            | *51 | Cowsar et al., "Poly (lactide-co-glycolide) Microcapsules for Controlled Release of Steroids" Methods in Enzymology 112 (Drug and Enzyme Targ) 101-116 (1985)   |
| VR            | *52 | Eldridge et al., "Biodegradable and Biocompatible Poly (DL-lactide-Co-Glycolide) Microspheres as an Adjuvant for Staphylococcal Enterotoxin B Toxoid Which Enhances the Level of Toxin Neutralizing Antibodies" Infection and Immunity 59(9):2978-86 (1991) |
| VR            | *53 | Eldridge et al., "Biodegradable Poly (DL-lactide-coglycolide) Microspheres" Res. Immunol. 143(5) 557-63 (1992)  |
| VR            | 54  | Esparza et al., "Parameters Affecting the Immunogenicity of Microencapsulated Tetanus Toxoid" Vaccine 10(10): 714-720 (1992)  |
| VR            | *55 | Glaser, V., "Solving the HIV Vaccine Puzzle: Questions Still Outnumber the Answers" Genetic Engineering News pps. 15-30 (November 1, 1993)  |
| VR            | 56  | Hora, et al., "Release of Human Serum Albumin from Poly(lactide-co-glycolide) Microspheres" Pharmaceutical Research 7(11):1190-1194 (1990)  |
| VR            | *57 | Hu et al., "Effect of immunization with a vaccinia-HIV env recombinant on HIV infection of chimpanzees" Nature 328 (6132):721-723 (August 1987)   |
| VR            | *58 | Kensil et al., "Development of a genetically engineered vaccine against feline leukemia virus infection" J. Amer. Veterinary Med. Assoc. 199(10):1423-1427 (1991)   |
| VR            | 59  | Kohn et al., "Single Step Immunization Using a Controlled Release, Biodegradable Polymer With Sustained Adjuvant Activity" J. Immun. Methods 95:31-38 (1986)  |
| VR            | *60 | Maulding, "Prolonged Delivery of Peptides by Microcapsules" J. of Controlled Release 6:167-176 (1987)   |
| VR            | 61  | Nellore et al., "Evaluation of Biodegradable Microspheres as Vaccine Adjuvant for Hepatitis B Surface Antigen" Journal of Parenteral Science & Technology, Vol. 46, No. 5: 176-180 (September-October 1992)   |
| Not Available | *62 | Nunberg et al., "Adjuvant Formulations to Increase the Virus-neutralizing Antibody Response to HIV-1 rgp120 Subunit Vaccine" Vaccines (Annu. Meet.), Norrby et al., 11th edition, N.Y.: Cold Spring Harbor Lab Vol. 94:23-27 (Mod. Approaches New 1994).    |

|  |                              |
|--|------------------------------|
| EXAMINER <u>VR</u>   | DATE CONSIDERED <u>10/99</u> |
| <b>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s).</b> |                              |

|  |                                      |                               |
|--|--------------------------------------|-------------------------------|
|  | <b>ATTY. DOCKET NO.</b>              | <b>SERIAL NO.</b>             |
|  | 14918-707 CPA4                       | 08/846,933                    |
|  | <b>APPLICANT</b><br>Cleland et al.   |                               |
|  | <b>FILING DATE</b><br>April 30, 1997 | <b>GROUP ART UNIT</b><br>1641 |

|    |     |   |
|----|-----|---|
| VR | *63 | O'Hagan et al., "Biodegradable Microparticles as Controlled Release Antigen Delivery System" <u>Immunology</u> 73(2):239-242 (1991)   |
| VR | 64  | Payne et al., "Water Soluble Phosphazene Polymers for Parenteral and Mucosal Vaccine Delivery" <u>Vaccine Design: The Subunit Adjuvant Approach</u> , Powell et al., New York, NY: Plenum Press Vol. 6:473-493 (1995)               |
| VR | 65  | Preis, "A Single-step Immunization by Sustained Antigen Release" <u>J. Immun. Methods</u> 28:193-197 (1979)   |
| VR | *66 | Putney, S., "How Antibodies Block HIV Infection: Paths to an AIDS Vaccine" <u>TIBS</u> 17:191-196 (1992)  |
| VR | 67  | Singh et al., "Controlled Delivery of Diphtheria Toxoid Using Biodegradable Poly (D,L lactide) Microcapsules" <u>Pharmaceutical Research</u> 8(7): 958-961 (1991)   |
| VR | *68 | Tabata et al., "Activation of Macrophage in Vitro to Acquire Antitumor Activity by a Muramyl Dipeptide Derivative Encapsulated in Microspheres Composed of Lactide Copolymer" <u>Journal of Controlled Release</u> 6:189-204 (1987) |
| VR | 69  | Watts et al., "Microencapsulation Using Emulsification/Solvent Evaporation: An Overview of Techniques and Applications" <u>Critical Reviews in therapeutic Drug Carrier Systems</u> , Vol. 7, Issue 3: 235-259 (1990)               |
| VR | *70 | White et al., "A purified Saponin Acts as an Adjuvant for a T-independent Antigen" <u>Immunobiology of Proteins and Peptides VI</u> , M.Z. Atassi, New York:Plenum Press pps. 207-210 (1991)  |
| VR | *71 | Wu et al., "Saponin Adjuvant Enhancement of Antigen-Specific Immune Responses To An Experimental HIV-1 Vaccine" <u>J. of Immuno.</u> 148(5):1519-1525 (1992)  |

|   |                              |
|---|------------------------------|
| EXAMINER <u>V. R.</u>   | DATE CONSIDERED <u>16/99</u> |
| EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant(s). |                              |